REMARKS

The claims

New claims 13-15 are fully supported in the specification, *e.g.*, at page 8, lines 5-16.

The specification

There is no need to physically incorporate from Madgwick *et al.* the sequence disclosed therein of the SLIM 3 polypeptide. This sequence is well-known in the art, and is available to the public, as is indicated by the fact that it has been published. One of ordinary skill can readily obtain the sequence from, *e.g.*, the Madgwick reference. Because of its public availability, the sequence is not "essential material" required to establish enablement. Therefore, the sequence need not be physically present in the specification. The rejection should be withdrawn.

Rejections under 35 USC 112, second paragraph

The rejections under 35 USC 112, second paragraph are untenable. One of skill in the art would understand from the language in the claims, particularly in view of the disclosure in the specification, what is meant by the term "biologically active." It is clear that the SLIM3, or a biologically active fragment thereof, exhibits an activity of regulating transcriptional activating activity of human AR or human ERβ; and that both AR and ERβ, or biologically active fragments thereof, exhibit the activity of regulating transcription.

As for the rejections over the terms AR, ERβ and SLIM 3, these terms are well-known in the art and do not need to be delineated further in the claims. Nevertheless, in an effort to expedite prosecution, the claims have been amended to spell out, at their first occurrence in the claims, the full meaning of each acronym. The amendments were not made for purposes of patentability and do not narrow the scope of the claims.

Rejection under 35 USC 112, first paragraph

With respect to the enablement rejection, applicants disagree with the allegation that the specification lacks enablement for the full scope of "biologically active derivatives thereof." However, in the interest of expediting prosecution, the claims have been amended to recite "biologically active fragments thereof." Applicants reserve the right to pursue any canceled subject matter in continuing applications.

Methods of generating fragments of a polypeptide of known sequence, as in the present case, are routine and conventional in the art. Furthermore, as the Examiner acknowledges, the specification teaches routine, conventional methods to determine whether any particular peptide fragment exhibits the claimed biological activity. For example, assays for SLIM3 activity are disclosed in references cited in the instant application; see, *e.g.*, the specification at page 11, line 29 to page 12, line 6. A typical assay for SLIM3 activity is exemplified in example 2, in which the ability of SLIM3 to interact with, and to stimulate the expression of, AR is measured. Other assays for SLIM3 activity are presented in Example 3. Assays for AR and ERβ are also routine and conventional. Typical assays are disclosed in references referred to in the specification. For AR assays, see, *e.g.*, page 12, lines 7-24; for ERβ assays, see, *e.g.*, page 13, lines 7-25. See also Examples 2 and 3, which present assays for both AR and ERβ. It would not require undue experimentation to make a fragment and to determine if it exhibits such activity.

When the sequence of a polypeptide is known, as in the present case, the recitation of "fragments thereof," particularly of "biologically active" fragments thereof, is consistent with PTO Guidelines. See, *e.g.*, the Training Materials regarding Written Description, Example 14, which discusses a fact scenario in which variants of a protein of known sequence are claimed as

having 95% identity to those sequences and retaining its activity; the variants include "substitutions, deletions, insertions and additions." The Guidelines state that such claims have adequate written description and thus are acceptable claims.

In view of the above, there is no need for applicants to provide "actual or prophetic examples" of such fragments, as stated by the Examiner.

The recitation of fragments of proteins whose sequence is known, wherein the fragments are defined in terms of functional properties of the protein, has often been deemed acceptable by the PTO, as is shown by the fact that many claims having such language are present in issued U.S. patents. See, *e.g.*:

USP 5,968,797, claim 1, which recites, *i.a.* "An isolated polypeptide comprising a member selected from ... (f) a polypeptide fragment of the amino acid sequence as set forth in SEQ ID NO: 4, wherein said fragment has enzymatic activity ..."

USP 6,130,051, claim 1, which recites "An isolated polypeptide comprising an amino acid sequence of a polypeptide fragment of the human inositol monophosphate polypeptide, wherein said human inositol monophosphate polypeptide consists of amino acid residues 1 to 265 of SEQ ID NO:2; and further wherein said fragment has inositol monophosphate activity."

USP 6,194,186, claim 1, which recites "An isolated and purified polynucleotide sequence encoding a human protein kinase (PK) comprising the amino acid sequence of SEQ ID NO: 1 or an enzymatically active fragment thereof."

USP 6,143,870, claim 2, which recites "A purified polypeptide comprising an immunologically active fragment of the amino acid sequence as shown in SEQ ID NO:2, wherein said fragment comprises at least 13 contiguous amino acid residues of SEQ ID NO:2."

USP 6,200,770, claim 1, which recites "An isolated polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO:11, wherein the fragment comprises at least 50 contiguous amino acids of SEQ ID NO:11, and wherein said polypeptide has kinase activity."

See *In re Cartwright*, 49 USPQ2d 1464 (Fed. Cir. 1999) regarding the weight to be given to prior PTO allowance of claims reciting the same terms as used in the claims at issue.

Rejection over alleged prior art

The allegation that the claims are anticipated by USP 5,789,170 is untenable. The '170 patent does not disclose a human AR or ERβ or a biologically active fragment thereof, as recited in the amended claims. Therefore, the cited patent does not anticipate the instant claims.

In view of the preceding amendments and argument, the application is believed to be in condition for allowance, which action is respectfully requested.

Respectfully submitted,

Nancy Axelrod (44,014) for
Richard M. Lebovitz (37,067)
Attorney for Applicants

Nancy Axelrod
Nancy J. Axelrod (44,014)
Patent Agent

Millen, White, Zelano & Branigan, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Blvd., Suite 1400
Arlington, VA 22201
Direct Dial: 703 812-5304

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A method of identifying agents that regulate the transcriptional activating activity of human AR or ERβ, comprising:

contacting a cell expressing human androgen receptor (AR) or human estrogen receptor β (ERβ), and, human skeletal muscle LIM protein (SLIM)3, or biologically-active ~~derivatives~~ fragments thereof, with a test agent; and

determining whether said test agent regulates the transcriptional activating activity of human AR or human ERβ.